

REMARKS

Claims 1-9, 11, and 23-31 are pending. Claims 23, 24, 26 and 27 have been withdrawn as directed to a non-elected invention.

Claims 1 and 7 have been amended to delete the transition word “comprising,” as it is inconsistent with reciting a compound. In addition, claims that recite specific chemical compounds or groups have been amended to be commensurate in scope with the elected species. The subject matter and claims that have been canceled have been canceled without prejudice to presenting it in a divisional application.

New claims 29, 30 and 31 recite the substituent for linking the CC-1065 analog to a cell-binding agent. Support for the claims is found at page 15, lines 7-22.

Accordingly, no question of new matter arises and entry of the amendment is requested, respectfully.

A) Claim Rejections - 35 U.S.C. § 112

(1) Claims 1-22, 25 and 28 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. According to the Examiner, the claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

The essence of the Examiner’s argument appears to be that claims 1-6 are too broad because the compounds are not described by specific formulas.

For the following reasons the rejection is traversed, respectfully.

As explained in the Declaration under 37 C.F.R. § 1.132 submitted herewith, an aspect of the invention claimed in claim 1 is an improvement on known CC-1065 analogs, wherein a prodrug is formed that serves to increase the solubility in aqueous solutions and to stabilize the seco-CBI moiety of the CC-1065 analogs through the reaction of the phenolic hydroxyl group to introduce a protecting group. Further, at the effective filing date of the above-identified application, numerous analogs of CC-1065 were known in the art. Accordingly, Applicants are entitled to claim prodrugs of any analog of CC-1065. That is, claim 1 should not be limited to the prodrugs that are defined by the specific formulae set forth in the specification and in claim 7.

This is in accord with the law of In re Herscheler (200 USPQ (BNA) 711 (CCPA 1979)). In Herscheler, the court found adequate written description support for broad claims to processes for topically administering a physiologically active steroidal agent to a human or animal by concurrently administering the steroidal agent and dimethyl sulfoxide (“DMSO”), even though the specification disclosed only one example of a “physiologically active steroidal agent.” The court found sufficient written description in Herschler because the invention was to the DMSO solvent, not the steroids and numerous physiologically active steroidal agents were known to those of ordinary skill in the art.

Similarly, in the present claim 1, the invention is to the protection of the phenolic group of the alkylating portions of an analog of CC-1065, not to the analog itself. Further, as of the effective filing date of the above-identified application, numerous analogs of CC-1065 were known to those of ordinary skill in the art. See, for example, the discussion in the declaration and in the specification at page 4, lines 1-12.

In view of the above, Applicants submit that requiring claims 1-6 to be limited to a specific formula goes against the established law. Accordingly, the Examiner is requested, respectfully, to remove this rejection.

(2) Claims 1-22, 25 and 28 were rejected under 35 U.S.C. § 112, first paragraph as not being enabled. The Examiner asserted that while the specification is enabling for a prodrug of an analog of CC-1065, wherein the analog is formed from a first subunit of formula (I) covalently linked to a second subunit of the formula (V), it does not reasonably provide enablement for a prodrug of an analog of CC-1065, wherein the analog is formed from a first subunit of formula (I) covalently linked to a second subunit other than one of the formulae (II)-(IX).

For the following reasons, the rejection is traversed, respectfully.

As explained in the declaration under 37 C.F.R. § 1.132, as of the effective filing date of the above-identified application, one of ordinary skill in the art could readily make any analog of a CC-1065 and any prodrug of such analogs encompassed within the present claims 1-6, as well as those prodrugs that are specifically defined in the specification by reference to a particular formula. Accordingly, the Examiner is respectfully requested to reconsider and remove this rejection.

B) Claim Rejections - 35 U.S.C. § 112

Claims 1-22, 25 and 28 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner asserted that it is inconsistent to use the word comprising to describe a compound.

The claims have been amended to delete the transition word “comprising.”

C) Objections

(1) Claims 1-22, 25 and 28 were objected to as containing non-elected subject matter, i.e., a phosphate protecting group of variable R_7 of formula (I), formula (II), (III), (IV), (VI), (VII), (VIII), and (IX), etc. The Examiner suggested the Applicants amend the claims to the scope of the elected subject matter.

Independent claim 7, reciting specific formulae, has been amended to be commensurate in scope with the elected subject matter, as has been claim 4, reciting specific protecting groups.

However, for reasons discussed above, Applicants submit that they are entitled to claims that are not limited to a specific formula. Accordingly, independent claim 1 has not been so amended. Rather, the Examiner is requested to consider Applicants' comments above and allow claims commensurate in scope with the scope of the invention, which is prodrugs of any analog of CC-1065, many of which were known to those skilled in the art as of the effective filing date of the present application.

(2) Claims 17-22 were objected to as containing non-elected subject matter. Specifically, the Examiner asserted that none of the compounds in claims 17-22 contains the elected subject matter.

Claims 17-22 have been canceled without prejudice to presenting them in a divisional application.


D) Rejoinder of claim 26

Should either of composition claims 6 or 25 be found allowable, applicants request that claim 26, which claims methods of using the compositions according to claim 6 or 25 be rejoined.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,


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